

**UNITED STATES DEPARTMENT OF COMMERCE****Patent and Trademark Offic**

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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
|-----------------|-------------|----------------------|---------------------|

09/066,255 04/24/98 BUECHLER

K 234/116

HM22/0829

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EXAMINER

GARCIA, M

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1627

DATE MAILED:

08/29/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

File Copy

| | | |
|------------------------------|---|---------------------------------------|
| Office Action Summary | Application No. 09/066,255 | Applicant(s) Buechler et al |
| | Examiner Mauri E. Garcia, Ph. D. | Group Art Unit 1627 |
| |  | |

Responsive to communication(s) filed on Jun 5, 2000

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle* 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire THREE month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

Claim(s) 23-35 is/are pending in the application.

Of the above, claim(s) 23-27, 29, 31, 33, and 35 is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 28, 30, 32, and 34 is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 8

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

DETAILED ACTION

1. The response filed June 5, 2000 is acknowledged. Claims 28 and 30 were amended and no claims were added or cancelled. Currently, claims 23-35 are pending. Further consideration has necessitated a new rejection. Since the new rejection was not brought about by the amendment to the claims, the case is maintained in the non-final stage. However, new grounds of rejection necessitated by applicant's amendment are also included in this action.

2. This case contains claims 23-27, 29, 31, 33 and 35 that are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions, the requirement being traversed in Paper No. 5.

New Grounds of Rejection (not necessitated by amendment)
Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 28, 30, 32 and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims contain the term "ligand analogue", which is deemed to be indefinite. It is not clear what are the similarities and differences between the ligand and the ligand

analogue; that is, how "analogous" must these two compounds be? Thus, it is impossible to determine the metes and bounds of the invention and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

New Grounds of Rejection (necessitated by amendment)
Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 30 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Margaron et al (J. Photochem. Photobiol. B 1992-on PTO-1449, Paper No. 8) in view of Renzoni et al (US 5,135,717) further in view of Freytag (US 4,434,236).

Margaron et al teach water-soluble hybrid phthalocyanine derivatives (see Figure 1). The compounds taught by the reference consist of phthalocyanines where at least two of the four pyrrole moieties comprise a different number of rings (see in Figure 1, compounds labeled **M-N₂SB₂P** (cis and trans)). The photodynamic properties of the compounds are studied in biological systems (see Abstract). The compounds have superior absorption properties due to “the perturbation of the (na)phthalocyanine D_{4h} symmetry and the modification of the acennalation” (see page 188, 1st two paragraphs). Margaron et al lacks the teaching of using these compounds in a conjugate.

However, use of phthalocyanine derivatives in conjugates was well known in the art at the time of filing. Renzoni et al teach water-soluble phthalocyanine derivatives (see column 3, lines 29-55) that read directly on those of the instant claims. These phthalocyanines are conjugated to biologically active agents such as antibodies (column 39, lines 1-25), peptides or nucleotides (see claim 3 of the reference). The conjugates can be used in biological assays (see Example 16, column 39). The Renzoni reference lacks the specific teaching of a competitive assay as recited in the claims.

However, one of ordinary skill in the art would know that such labeled antibodies could be used in a competitive assay, because such assays were very well known in the art at the time of filing. For example, Freytag teaches an assay that is the same as the one claimed, except for the fact that Freytag uses different labels for the antibodies than the ones of the instant claims (see Abstract, Examples and claims 1-7 of the reference).

However, Freytag does discuss that fluorophores can be used for labeling the antibodies (column 3, lines 43-48).

Therefore it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use the water-soluble hybrid phthalocyanine derivatives of Margaron et al in a conjugate, as taught by Renzoni et al, and to further use these compounds as the fluorescent tags in the method of Freytag. A person of ordinary skill in the art would have been motivated to make such a substitution to use a fluorophore with "more ideal spectral properties" as taught by Renzoni et al (column 1, lines 49-52); specifically, the fluorophore of Margaron et al would have preferable properties based on its asymmetry.

8. Claims 28 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Margaron et al (J. Photochem. Photobiol. B 1992-on PTO-1449, Paper No. 8) in view of Renzoni et al (US 5,135,717) and further in view of Freytag (US 4,434,236) as applied to claims 30 and 34 above, and further in view of Stanton et al (US 4,803,170).

The teachings of Margaron et al concerning water-soluble hybrid phthalocyanine derivatives are set forth *supra*. Also, the combination of Renzoni et al and Freytag teach that water-soluble phthalocyanine derivatives conjugated to biomolecules can be used in a competitive assay, as discussed *supra*. None of these references discloses the configuration of bound ligand analogue in step b (claim 28) and furthermore the prior binding to a solid phase (claim 32) recited in the instant claims.

However, one of ordinary skill in the art would know that such a configuration could be easily achieved, and would simply be a design choice in the creation of the assay set-up. Such assays were well known in the art at the time of filing. For example, Stanton et al discusses a competitive assay where the analyte conjugate and ligand/marker binding partner are both bound to a solid phase (Abstract and column 3). Most importantly, “excess analyte conjugate becomes sequestered...on a surface, where its marker activity can be read as an indication of analyte presence” (column 3, line 66 – column 4, line 1).

Therefore it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use the water-soluble hybrid phthalocyanine derivatives of Margaron et al in a conjugate, as taught by Renzoni et al, and to further use these compounds as the fluorescent tags in the method of Freytag. A person of ordinary skill in the art would have been motivated to make such a substitution to use a fluorophore with “more ideal spectral properties” as taught by Renzoni et al (column 1, lines 49-52); specifically, the fluorophore of Margaron et al would have preferable properties based on its asymmetry. One would be additionally motivated to use the bound configuration of Stanton et al to create a more facile assay, as taught by the reference (column 1, lines 9-18).

Response to Arguments

9. Applicant's arguments filed June 5, 2000 have been fully considered but are moot in view of the new ground(s) of rejection.

Status of Claims/ Conclusion

10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie E. Garcia, Ph.D. whose telephone number is (703) 308-0065. The examiner can normally be reached on Monday-Thursday and alternate Fridays from 8:30 to 6:00.

12. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat, can be reached on (703) 308-2439. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



DR. JYOTHSNA VENKAT PH.D
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Maurie E. Garcia, Ph.D.
August 28, 2000